510(K) Summary

JAN 21 2009

K083795

Submitter	Cynosure, Inc 5 Carlisle Road Westford, MA 01886
Contact	George Cho Senior Vice President of Medical Technology
Date Summary Prepared	December 19, 2008
Device Trade Name	Cynosure Smartlipo MPX Laser
Common Name	Medical Laser System
Classification Name	Instrument, surgical, powered, laser 79-GEX 21 CFR 878 4810
Equivalent Device	The Cynosure YAG Family laser
Device Description	The Cynosure Smartlipo MPX laser with SmartSense T Module is a Nd YAG laser, having a ND YAG crystal rod as a lasing medium It is a laser with a wavelength of 1064 nm and 1320 nm Laser activation is by footswitch Overall weight of the laser is 285lbs, and the size is 41"x18"x32" (HxWxD) Electrical requirement is 220 VAC, 20A, 50-60 Hz, single phase
Intended Use	The SmartLipo MPX Laser is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands The SmartLipo is further indicated for laser assisted lipolysis
Comparison	The Cynosure Smartlipo MPX Laser with SmartSense T Module has the same indications for use, the same principle of operation, and the same laser parameters as the predicate device(s)
Nonclinical Performance Data	none
Clinical Performance Data	none
Conclusion	The Cynosure Smartlipo MPX Laser with SmartSense T Module is a safe and effective device for the 'indications for use' specified
Additional Information	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2009

Cynosure, Inc
% Mr George Cho
Senior Vice President
5 Carlisle Road
Westford, Massachusetts 01886

Re K083795
Trade/Device Name Cynosure Smartlipo MPX Laser with SmartSense T Module
Regulation Number 21 CFR 878 4810
Regulation Name Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class II
Product Code GEX
Dated December 19, 2008
Received December 22, 2008

Dear Mr Cho

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K083795

Device Name Cynosure Smartlipo MPX Laser with SmartSense T Module

Indications For Use

The Cynosure Smartlipo MPX Laser is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands The Cynosure Smartlipo MPX Laser is futher indicated for laser assisted lipolysis

Prescriptive Use X OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM 1/21/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083795